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NOTICE OF ALLOWANCE AND FEE(S) DUE

22852 7590 01/28/2009 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER

HABTE, KAHSAY

901 NEW YORK AVENUE, NW

EXAMINER PAPER NUMBER ARTHNIT

1624 DATE MAILED: 01/28/2009

LIP WASHINGTON, DC 20001-4413

TITLE OF INVENTION: COMPOUNDS, COMPOSITIONS, AND METHODS

APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO 10/552.611 09/20/2006 Xiangping Oian 09367.0054-00000

APPLN, TYPE SMALL ENTITY ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE nonprovisional YES \$755 \$300 \$1055 04/28/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown

B. If the status above is to be removed, check box 5b on Part B -Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

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INSTRUCTIONS: This appropriate. All further c indicated unless correcte maintenance fee notificate	form should be used I correspondence including d below or directed off	or transing the Parierwise i	nitting the ISSU stent, advance of n Block 1, by (a	TE FEE and PUBLICA' ders and notification of a) specifying a new corr	TION FEE (if requestion of the control of the contr	ired). I vill be ; and/o	Blocks 1 through 5 sh mailed to the current r (b) indicating a sepa	tould be completed where correspondence address as rate "FEE ADDRESS" for	
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FINNEGAN, H LLP 901 NEW YORK	AVENUE, NW		OW, GARR	ETT & DUNNER	Cereby certify that the	rtificate	of Mailing or Trans		
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APPLICATION NO.	FILING DATE			FIRST NAMED INVENTO	OR AT		RNEY DOCKET NO.	CONFIRMATION NO.	
10/552,611	09/20/2006			Xiangping Qian	09367.0054-00000			6327	
TITLE OF INVENTION:	COMPOUNDS, COM	POSITIO	NS, AND METI						
APPLN, TYPE	SMALL ENTITY	ISSU	JE FEE DUE	PUBLICATION FEE DUE		E FEE	TOTAL FEE(S) DUE	DATE DUE	
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☐ Publication Fee (No small entity discount permitted) ☐ Advance Order - # of Copies				☐ Payment by credit card. Form PTO-2038 is attached. ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number (enclose an extra copy of this form).					
	SMALL ENTITY state	is. See 37		b. Applicant is no lo					
NOTE: The Issue Fee and interest as shown by the re	Publication Fee (if req ecords of the United Sta	uired) wi tes Paten	ll not be accepted t and Trademark	from anyone other than Office.	the applicant; a reg	istered .	attorney or agent; or th	e assignee or other party in	
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22852	7590 01/28/2009		EXAMINER		
FINNEGAN,	HENDERSON, FARA	HABTE, KAHSAY			
LLP		ART UNIT	PAPER NUMBER		
	K AVENUE, NW J DC 20001-4413	1624			

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 435 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 435 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Application No. Applicant(s) 10/552.611 QIAN ET AL. Notice of Allowability Examiner Art Unit Kahsay T. Habte 1624 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. This communication is responsive to . The allowed claim(s) is/are 1-38. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). b) \(\subseteq \text{Some*} \) c) \(\subseteq \text{None} \) of the: 1. T Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: _____. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1. | Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application 2. Notice of Draftperson's Patent Drawing Review (PTO-948) Interview Summary (PTO-413), Paper No./Mail Date Information Disclosure Statements (PTO/SB/08). 7. X Examiner's Amendment/Comment Paper No./Mail Date 10/6/2005 4. T Examiner's Comment Regarding Requirement for Deposit 8. X Examiner's Statement of Reasons for Allowance of Biological Material 9. ☐ Other .

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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Lauren Stevens on Jan. 12, 2009. Enter the following:

- In claim 1 (page 3, lines 23-26), delete the phrase "; a pharmaceutically acceptable solvate of a compound of Formula I; or a pharmaceutically acceptable solvate of a pharmaceutically acceptable salt of a compound of Formula I".
 - 2. In claims 2-21 (line 1), replace the phrase "comprising" with --wherein--.
 - 3. In claim 3 (page 4, line 1), replace "claim 2" with --claim 1--.
 - 4. In claim 4 (page 5, line 1), replace "claim 3" with --claim 1--.
 - 5. In claim 5 (page 5, line 1), replace "claim 4" with --claim 1--.
 - 6. In claim 6 (page 5, line 1), replace "claim 5" with --claim 1--.

- 7. In claim 8 (page 6, line 1), replace "claim 7" with --claim 1--.
- 8. In claim 9 (page 7, line 1), replace "claim 8" with --claim 1--.
- 9. In claim 10 (page 7, line 1), replace "claim 9" with --claim 1--.
- 10. In claim 11 (page 7, line 1), replace "claim 10" with --claim 1--.
- 11. In claims 13-15 (page 8, line 1), replace "claim 12" with --claim 1--.
- 12. In claims-16-17 (page 9, line 1), replace "claim 12" with --claim 1--.
- 13. In claim 18 (page 10, line 1), replace "claim 17" with --claim 1--.
- 14. In claim 19 (page 10, line 1), replace "claim 18" with --claim 1--.
- 15. In claim 21 (page 10, line 1), replace "claim 20" with --claim 1--.
- 16. Delete claims 39-43.

Information Disclosure Statement

Applicant's Information Disclosure Statement, filed on 10/06/2005 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: claims 1-38 are free from prior art. The closest prior art is Santilli et al. *Journal of Heterocyclic Chemistry* (1979), 16(2), 213-216. Santilli et al. discloses 1,2,4-oxadiazine compounds with R2 and R2' = oxo that is different from the instant claims. R2 and R2' together forming an oxo group is not taught or suggested in the instant claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance"

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone Application/Control Number: 10/552,611 Page 5

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number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kahsay T. Habte/ Primary Examiner, Art Unit 1624 January 28, 2009 Application/Control Number: 10/552,611 Page 6

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